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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,699	09/08/2000	Birgit Oppmann	DX01042X	3652

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EXAMINER	
DECLOUX, AMY M	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/04/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/658,699	OPPMANN ET AL.	
	Examiner	Art Unit	
	Amy M. DeCloux	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2002 and 15 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-62* is/are pending in the application.

4a) Of the above claim(s) *59-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IV, Claims 14-16 and 19, now cancelled and replaced with newly added corresponding claims 51-58, in Paper No. 10, filed 1-29-02, is acknowledged. The traversal is on the ground(s) that a search of Group IV (drawn to a binding compound comprising an antigen binding site from an antibody which specifically binds to a mammalian IL-B30/p40 complex) will yield information regarding Group V, Claims 17-18, now cancelled and replaced with newly added claims 59-62. This is not found persuasive because a search of Group V (drawn to a method of producing an immunocomplex of an antigen:binding compound) is distinct from a search of Group IV for the reasons given in the restriction mailed 12-13-01 (Paper No. 6); specifically, Groups IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, a binding compound comprising an antigen binding site, can be used in affinity purification methods, as well as in a method of producing an antigen:antibody complex. As such Groups IV and V have acquired a separate status in the art because of their recognized divergent subject matter.

MPEP 803 states that: "For the purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or different field of search. Furthermore, since Groups IV and V have a separate classification as indicated in the above mentioned restriction requirement, a search in the non-patent literature of the elected product of Group IV, while overlapping to some extent, would not be co-extensive with a search of the non-elected method of Group V. Since an examination and search of Group IV and Group V in a single application, would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election without traverse of the species SEQ ID NO:2 and human p40, in Paper No. 16, filed 9-18-02, is acknowledged. Since no prior art was found, the species requirement has been withdrawn.

Claims 51-62 are pending.

Claims 59-62 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10, filed 1-29-02.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A) Claims 51-58 are drawn to a binding compound which comprises an antigen binding site from an antibody which specifically binds to a mammalian IL-B30/p40 complex and a pharmaceutical composition thereof, (claims 51-52 and 54), and a binding compound which comprises an antigen binding site from an antibody which specifically binds to a fusion protein comprising an IL-B30 subunit (SEQ ID NO:2 or 4) and a p40 subunit of murine or human origin (claims 55-56 and 58), wherein said binding compound neutralizes at least about 90% of the bioactivity of the IL-B30/p40 complex (claim 53) or of the fusion protein comprising and IL-B30 subunit (SEQ ID NO:2 or 4) and a p40 subunit of murine or human origin (claim 57). These claims all encompass the limitation that the product is not substantially immunologically reactive with any epitope presented by either IL-B30 alone or p40 alone.

The specification discloses on page 3 that the present invention is based upon the discovery that the p40 subunit of IL-12 also associates with the ILB30 cytokine. It is noted that the post filing date reference of Oppmann et al. (Immunity 13:715-725)(2000) teaches that IL-23 is a cytokine that is a heterodimer comprising the P40 subunit of IL-12 and a P19 subunit (see entire article, including the Abstract). It is noted that said that the P19 subunit of mouse and human has sequence identical to that of the instantly recited IL-B30 cytokine sequences of SEQ ID NOs:2 and 4.

Section V of the instant specification discloses that antibodies can be raised to various epitopes of the p40/IL-B30 proteins, and that neutralizing antibodies can be useful in competitive binding assays. Page 14 discloses that depletion or absorption methods can be used to deplete antibodies which bind to either polypeptide component alone. However the specification does not describe a single exemplification of an antibody that is not substantially immunologically reactive with any epitope presented by either IL-B30 alone or p40 alone. Furthermore the specification does not describe a single epitope of an IL-B30/p40 complex or fusion protein that

is not shared with either IL-B30 alone or p40 alone. Thus the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997).

The Court further elaborated that generic statements are not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. Finally, the Court indicated that while applicants are not required to disclose every species encompassed within a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, defined by nucleotide sequence, falling within the scope of the genus, See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Although the instant claims do not encompass DNA molecules, the same principle is applied to protein molecules such as antibodies.

Accordingly it is not sufficient to define a binding compound by its principal biological activity, IE that the product is not substantially immunologically reactive with any epitope presented by either IL-B30 alone or p40 alone, especially in view of the limited written description regarding the structure of an IL-B30/p40 complex or fusion protein. Pages 41-42 of the specification disclose that Il-12p40 and IL-B30 coprecipitate when nucleic acid molecules encoding IL-12p40 and IL-B30 are cotransfected into cells, but provide no further description of the complex, nor of antibodies directed to said complex. Pages 42-43 disclose that a fusion protein was generated from a construct with the IL-12 P40 signal sequence linked to an Nterminal FLAG epitope fused to the mature IL-12p40 sequence fused to a SER/GLY rich linker sequence of appropriate length fused to the mature sequence of IL-B30, but provide no further description of the complex formed, nor of antibodies directed to said fusion protein. Regarding the description of neutralizing antibodies, the instant specification discloses on page 12 lines 31-35 that the association of the IL-12 p40 subunit with IL-B30 has been confirmed, and if the two functionally associate, they might act together in the fashion of IL-12. In view of the ambiguity regarding the function of said complex, the claimed neutralizing antibodies have also not been clearly described. Based on the lack of representative species of antibodies and based on a lack of structural information of an IL-B30/p40 complex or fusion protein, one of skill would not know if they were in possession of the claimed binding compound or pharmaceutical composition thereof, without a further description from the specification.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See Vas-Cath, page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath, page 1116.). Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

B) Claims 53 and 57 are not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation "wherein said binding compound neutralizes at least about 90% of the bioactivity" of IL-B30/p40 complex (claim 53) or of the fusion protein comprising and IL-B30 subunit (SEQ ID NO:2 or 4) and a p40 subunit of murine or human origin (claim 57). There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes new matter.

It is noted that the specification discloses in Section V of the instant specification that antibodies can be raised to various epitopes of the p40/IL-B30 proteins, and that neutralizing antibodies can be useful in competitive binding assays. However, the examiner can find no disclosed written support for a binding compound which neutralizes at least about 90% of the bioactivity of the recited complex or fusion protein. Applicant is invited to point out support.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 51-58 are indefinite in their recitation of the phrase "is not substantially immunologically reactive" as recited in lines 5-6 of claim 51 and in line 5 of claim 55 because i) the extent of what is encompassed by the word substantially is not clear, and ii) because it is not clear what is encompassed by the phrase "immunologically reactive". Since the binding compound comprises an antigen binding site from an antibody, a phrase incorporating the concept of binding would be more acceptable.

B) Claims 54 and 58 are indefinite because, as recited, they read on a composition, and are therefore improperly dependent on compound Claims 51 and 55, respectively. Rewording the claims to recite something along the lines of a composition comprising the compound of claim 51 or 55, respectively, and a pharmaceutically acceptable carrier or diluent, would be one way to overcome the rejection.

C) Claims 52 and 56 are indefinite in their recitation of the phrase "wherein said binding compound is "humanized" because it is not clear how a compound, other than an antibody, is humanized. Inserting the word "antibody" after the word "humanized" is one way to overcome the rejection.

Claims 51-58 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.,
Patent Examiner, 1644
December 2, 2002

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